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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/284,297
Filing Date: July 05, 2000
Appellant(s): LEE ET AL.

ATTORNEY PAUL T. CLARK
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/21/07 appealing from the Office action mailed 5/17/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying **Related Appeals and Interferences** is contained in the brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 12-123,135-137, 146,147, 149 , 150 & 153 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The Terminal Disclaimer has been accepted & entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

CONSTANTZ	5962028	10-1999
CONSTANTZ	5782971	7-1998
CONSTANTZ	6005162	12-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

Claim 43, 127-131, 133, 134 are rejected under 35 U.S.C. 102(e) as being anticipated by CONSTANTZ 5962028.

Claim 43 requires a shaped compressed powder object comprising powders of Calcium Phosphate (CaP) and material to promote conversion of CaP to poorly crystalline

apatitic CaP (PCA).This composition, in comprising guise, does not exclude liquid, in fact as of instant dependent claim 127.

Constantz selects Ca carbonate, a crystalline growth inhibitor (col. 2, lines 35-56) ,one of the instant claim 133 promotors, & adds to CaP as dry powders (col. 5, lines 9 - 15,32-38) followed by mechanically mixing dry mixing, utilizing rollers,(col. 5,bottom - col. 6, top) thus creating compression of the mixed materials during the mixing process, with or without added water(col. 6, lines 10-21), the instant claim 127, 128 physiologic fluid . The instant compressed powder objects of poorly crystalline apatitic CaP would result, as the compositions are of less than 1.5 Ca/P (col. 4,line 61) , one of the criteria of a PCA as indicated @ page 12, lines 16 & 17 of the instant specification.The Reaction is endothermic, as of instant claim 129, as body temperature, (col. 6, line 51-61, col. 7, lines 60-col. 8 line 3) not exothermic conditions prevail in preparing bone fillers & implantable shaped structures strongly bioresorbable as of the instant products. Biological active agents added include bone morphogenic protein (col. 7, lines 5-8), the instant claim 131 & 134 bioactives, or supplemental materials

Claims 42, 43, 126-134 and 151-152 are rejected under 35 U.S.C. 102(e) as being anticipated by CONSTANTZ 5782971.

Claim 42 is a composite material of PCA , of Ca/P < 1.5, & a supplemental material, inclusive of CaP, selected to provide various characteristics, including adherence, tensile strength, resorption time, strength, hardness and elasticity of the composite.

Constantz provides an example of mixing of dry powders, including a CaP (considered as the instant supplemental ingredient) , the instant promoter, Ca carbonate, and amorphous calcium phosphate (ACP), & pressing . No liquid is added, thus claim 43 is also anticipated.

Dicalcium phosphate dehydrate &/or other promoters(col.4, lines 12-23) prepared by dry mixing ACP powders , then hydrating (col.5, lines 11-28, col.9, lines 29 -39) are also taught, & can be packed or inserted into an appropriate body site to harden (col. 6, lines 35 –40).

The lubricant is water or other physiological lubricant (col. 8, line 28-31).

Ca/P is as low (col. 5,lines 5-10) as 1.1 to 2 (less than 1.5) as instantly claimed, inclusive of CPA & ACP ratios of Ca/P.

The products are bio resorbable,biocompatible, applicable as a paste in vivo (col. 6, lines 1 1-39), to harden, or can be used as implants, or prosthetic devices (last paragraph, col. 6). Note the paste does not set up, but is injectable, at room temperature (col. 6, line 27-55) and sets at body temperature - thus, endothermîc (col. 8, lines 48-50). Active additives are at col. 6, top., Claim 151 is met, at col. 6 lines 47-50, and, since the same components are those instantly utilized, at the same compression strength, so would the density be the same. Claim 152 is met as the CaP supplemental is powder,or particles .

Claim Rejections - 35 USC § 103

Claims 40, 43, 103, 111- 120,124-134, 138-143, 145, 148, 151-152 are rejected under 35 U.S.C. 1O3(a) as being unpatentable over Constantz-5782971 –in view of Constantz et al – 6005162.

Constantz –5782971 (above) , uses the instant components, mixed as powders, with lubricant physiologic fluids added to provide wet mixing, or added after mixing, followed by compression. The instant claim 40 compression followed by hydration is not clearly recited at Constantz, although the reiteration in the patent of dry mixing, with wet ingredients then added, followed by shaping, molding , packing & the like (as at col. 6, lines 35-39) & to filling voids in bones(col. 6, lines 58-62) would make it evident to the artisan that the process of the instant compression.

Instant claim 103 also is not clearly recited; however, if one reads the compressed powder object to permit of liquid, the Constantz lubricants, as permitted under the comprising guise, then the method of 103 also becomes obvious, as filling bone voids with the composition is a method of treating a bone defect.

Instant claim 138 requires introducing the CaP & promoter with lubricant into a mold, not so pointed to by Constantz. However, a prosthetic implant is suggested (col. 6, lines 58-60) , thus one would recognize formation of such a product would be done using a mold.

Lyophilization is shown for ACP , & thus within the skill of the artisan to perform, for future powder use (Col. 7, line 40-44).

Neither are all supplemental components instantly claimed discussed. These components are optional additives well known to be used for their intended purposes & applied to optimize the benefits of utilization of the CaP materials, & are given no patentable weight.

However, 6005162 shows them (col. 5, lines 43- line 67, col. 7) for these purposes. This reference is directed at repairing boned defects, & expands on the advantages & preparation of the CaP compositions of the earlier patent. ACP is also addressed, in as much as the Ca/P ratio (col. 3, line 16-line 24, col. 4) , particle size, & forms of Ca-P used are within the parameters of ACP and of PCA with ratio adjustable to tailor the resorption rate from 2 weeks to 48 months(col. 3, lines 34-38) . Preparation by mixing in a number of equipment inclusive of those resulting in compression, rollers, mortar & pestle, is explained,as monitored by artisan to provide the desired physical characteristics (col. 4, lines 37-53) . Dry mixes are seen as storable for long periods(col. 5 line 36-43) free of liquid. The amount of water added, if any, alters the mechanical properties & setting time(col. 5, lines 22-30).

Mixing of dry components is stated to permit of partial reaction; this process results in enhanced setting times & reduces the amount of water needed to be added. Application to sites of interest involve setting at Body temperature, in presence of physiological fluids (col 7, lines 27-38), and in treating bone defects(col. 7, lines 50 – 58), as of instant claim 103.

Also, the dry ingredients can be mixed, with added hydrating or lubricating wet Ingredients , kneaded, rolled, & packed--- the instant compression-(col. 7, lines 17-22, 27-30) for in situ application. A discussion of use as drug delivery vehicles & orthopedic implants, the preparation of which is not indicated to require forming, molding, or other such compression resultant processes, is at column 7, lines 50-63. The remarks are made that the Constantaz compositions can provide tensile strength, fracture toughness, flexibility & other properties as desired, depending on addition of supplemental materials.

The instant dependent claims are met, as the references cite the compositions to be prepared within a 1.1 to 2, & particularly inclusive of the use of the ACP with Ca carbonate, utilized to reduce crystalline formation, &/or Dicalcium phosphate dehydrate,both of which are the instant claimed promoters of PCA formation, with endothermic reaction , since body temperature permits of setting , with hydrating or lubricant being water,& bone regenerative protein & antibiotics constituting additional acceptable components.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an bone defect composition to prepare one of Constantz, with modification to use any of art recognized means to improve setting, dependent upon desired healing characteristics, shown by Constantz, 6005162. Motivation to use a specific additive is shown to be a function of desired effects, & art recognized , by Constantz, 6005162 and adjuvants and exact ratios and amounts

effects, such as control of setting time, strength, pharmacological effects,compatability, resorbability & stability.

The amounts and proportions & forms of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each ingredient to optimize the effect desired, such as enhanced setting time, strength, resorption , depending upon the particular parameter of interest, with consideration of compatibility of components with each other & with physiological tissue & fluids.

(10) Response to Argument

Appellants arguments where persuasive have resulted in withdrawl of rejections of some dependent claims, & of claims 40 & 42 over the '028 reference & 40 & 138 over the '971` reference, consequently arguments over these claims will not be addressed.

As to Constantz, '028, appellant argues compressed , not defined in the specification, is defined in a dictionary. Examiner finds the term can be taken in its broadest meaning; Constantz applies pressure, compression, via syringe, molding, kneading,shaping & forming in addition to the mixing seen as resulting in some degree of compression, although not the specific example as shown in the pellet formation of the instant specification at lines 25-27 on page 61, and of claims 149 & 150. Uniform dispersion of compressed powders is in accord with

both the instant claims & with the result of mixing by Constantz- we don't see a conflict.

As to Constantz '971, appellant argues that no compressed object was shown, prior to hydration. However, as the composition of 43 is in comprising guise, the hydration material is not excluded, claims 127 & 128 require it; thus 43 & dependent claims are seen as met by Constantz.

Claim 42 was rejected over '971 over a number of supplemental ingredients; Appellant argued they are no longer claimed, however, calcium phosphate is, & it is seen as present in 2 modes in the '971 patent (col. 8, III B.).

As to the obviousness rejection,

Appellant argues there is only a capability of one in the art to arrive at appellant's invention as of the rejection of record. However, in accord with the recent KSR decision ,127 s. Ct. 1727@ 1741, USPQ2 d 1385, there is recognition that one in the art would be able to address references such as the 2 Constanz CaP Bone treatment patents & follow the teachings. Minimal testing would enable one to determine the CaP & additional Ca source materials needed & ratios thereof in order to prepare a bone defect composition of desired resorption, strength & setting characteristics; the '162 patent explains the basis of the use of components prepared as of the '971 patent.

Appellants argue that the rejected independent claims 40,42,43,103 all require compressing, & only mixing was present in the patents, while 138 requires a mold of a desired shape.

The compressing is seen as met by the incidental treatment of the mixing process, while explicit compressing was evident at col. 8, IIIA. Of the '971 patent, in the packing & testing of the formed CaP composition.

The mold use , unstated, is seen as obvious to the artisan to apply in order to produce the various implantable products attainable as made by Constantz preparation of ACP with other Ca sources & hydrating.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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PRIMARY EXAMINER

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